K010631

MAR 1 5 2001

510(k) Summary of Safety and Effectiveness: 21 CFR 807.92

Submitter's Name: Toshiba America Medical Systems, Inc.
Address: P.O. Box 2068,2441 Michelle Drive Tustin, CA 92781-2068
Contact: Paul Biggins, Regulatory Affairs Specialist
Telephone No.: (714) 730-5000

Device Proprietary Name: NEMIO, SSA-550A
Common Name: Ultrasound Imaging System

Classification:

Regulatory Class: II
Review Category: Tier II

Ultrasonic Pulsed Doppler Imaging System - Procode: 90-IYN
[Fed.Reg.No.:892.1550]
Ultrasonic Pulsed Echo Imaging System - Procode: 90-IYO
[Fed.Reg.No.:892.1560]
Diagnostic Ultrasonic Transducer - Procode: 90-ITX
[Fed. Reg. No.: 892.1570]

Identification of Predicate Devices:
Toshiba America Medical Systems believes that this device is substantially equivalent to the Following devices; SSA-370A/PowerVision 6000 Diagnostic Ultrasound System, 510(k) control number K991710; UIDM-400A/PowerView Ultrasound Workstation, 510(k) control number K992886; Siemens Omnia K992046
SSA-340A/Eccocee Diagnostic Ultrasound System, 510(k) control numbers K933747

Device Description:
The NEMIO will be offered in three variations all of which are mobile systems. These systems are all Track 3 devices that employ a wide array of probes that include flat linear array, convex linear array, and sector array with a frequency range of approximately 2 MHz to 12 MHz. The differences in systems will be the availability of various options such as size of monitor, ultrasonic, modes, and post processing display capablities.

Intended Use:
The NEMIO systems are intended to be used for the following type of studies; fetal, abdominal, intraoperative, pediatric, small organs, neonatal cephalic, adult cephalic, cardiac, transrectal, transvaginal, transesophageal, peripheral vascular, musculo-skeletal (both conventional and superficial), AND laparoscopic.

Safety Considerations:
These devices are designed and manufactured in conjunction with the Quality System Regulation, IEC- 60601 (applicable portions), the AIUM-NEMA UD2 Output Measurement Standard as applied to Track 3 Ultrasound systems and the AIUM-NEMA UD3 Output

Display Standard. This unit is similar to that of the Toshiba SSA-370A/PowerVision 6000 and engineering assessments identify no new issues of risk or safety.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 5 2001

Toshiba America Medical Systems, Inc.
C/O Mark Job, 510(k) Program Manager
TUV Product Service
1775 Old Highway 8 N.W.
Suite 104
NEW BRIGHTON MN 55112-1891

Re: K010631
Trade Name: NEMIO (Model SSA-550A) Diagnostic Ultrasound System
Regulatory Class: II/21 CFR 892.1550/CFR 892.1560
Product Code: 90 IYN/90 IYO
Dated: March 1, 2001
Received: March 2, 2001

Dear Mr. Job:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the NEMIO (Model SSA-550A) Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Numbers:

PLM-703AT
PC-19M
PSM-20CT
PSM-25AT
PEF-510MB
PVM-651VT
PSM-375AT
PLM-1202S
PVM-740RT
PEF-704LA

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note*: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded. The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

for Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Diagnostic Ultrasound Indications For Use Form

System X Transducer
Model NEMIO, SSA-550A
510(k) Number(s)

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal		n	n		n	n	n	n	n	
Abdominal		n	n	n	n	n	n	n	n	n
Intraoperative (small organs)		n	n	n		n	n	n	n	
Intraoperative Neurological										
Pediatric		n	n	n	n	n	n	n	n	n
Small Organ (Specify)		n	n	n		n	n	n	n	
Neonatal Cephalic		n	n	n	n	n	n	n	n	
Adult Cephalic		n	n	n	n	n	n	n	n	
Cardiac		n	n	n	n	n	n	n	n	n
Transesophageal		n	n	n	n	n	n	n	n	
Transrectal		n	n	n		n	n	n	n	
Transvaginal		n	n	n		n	n	n	n	
Transurethral										
Intravascular										
Peripheral Vascular		n	n	n		n	n	n	n	
Laparoscopic		n	n	n		n	n	n	n	
Musculo-skeletal Superficial		n	n	n		n	n	n	n	
Musculo-skeletal Conventional		n	n	n		n	n	n	n	
Endoscopic										
Other (specify)										

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments. Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; B-TDI; M-TDI

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K010631

Prescription Use (Per 21 CFR 801.109)

SK 4D

EXISTING TRANSDUCER TABLE

Transducer Model Number: PLM-703AT
510(k) Control Number: k991710

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (Specify)		P	P	P		P	P	P	P	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P		P	P	P	P	
Laparoscopic										
Musculo-skeletal Superficial		P	P	P		P	P	P	P	
Musculo-skeletal Conventional		P	P	P		P	P	P	P	
Other (specify)										

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M, B/PWD; BDF/PWD; BDF/MDF; B-TDI; M-TDI

NOTE: Originally submitted with SSA-370A (k991710)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seguin

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010631

Prescription Use (Per 21 CFR 801.109)

EXISTING TRANSDUCER TABLE

Transducer Model Number: PC-19M

510(k) Control Number: k991710

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Specify)										
Intraoperative Neurological										
Pediatric					P					
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac					P					
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Superficial										
Musculo-skeletal Conventional										
Other (specify)										

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments:_____

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K010631

Prescription Use (Per 21 CFR 801.109)

EXISTING TRANSDUCER TABLE

Transducer Model Number: PSM-20CT

510(k) Control Number: k991710

Clinical Application		Mode of Operation								
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic		P	P	P	P	P	P	P	P	
Adult Cephalic		P	P	P	P	P	P	P	P	
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Superficial										
Musculo-skeletal Conventional										
Other (specify)										

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; B-TDI; M-TDI

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Seymour

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K010631

Prescription Use (Per 21 CFR 801.109)

EXISTING TRANSDUCER TABLE

Transducer Model Number: PSM-25AT

510(k) Control Number: K933743

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify) –	Harmonic Imaging
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Specify)										
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P	P	P	P
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P	P	P	P	P	P	P
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Superficial										
Musculo-skeletal Conventional										
Other (specify)										

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; B-TDI; M-TDI

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David S. Segnar

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010031

Prescription Use (Per 21 CFR 801.109)

EXISTING TRANSDUCER TABLE

Transducer Model Number: PEF-510MB

510(k) Control Number: k991710

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal		P	P	P	P	P	P	P	P	
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Superficial										
Musculo-skeletal Conventional										
Other (specify)										

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; B-TDI; M-TDI

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David C. Yagmin

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010631

Prescription Use (Per 21 CFR 801.109)

EXISTING TRANSDUCER TABLE

Transducer Model Number: PVM-651VT

510(k) Control Number: k991710

Clinical Application		Mode of Operation								
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify) –	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal		P	P	P		P	P	P	P	
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Superficial										
Musculo-skeletal Conventional										
Other (specify)										

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; B-TDI; M-TDI

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seguin

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010631

Prescription Use (Per 21 CFR 801.109)

EXISTING TRANSDUCER TABLE

Transducer Model Number: PSM-375AT

510(k) Control Number: k991710

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify) –	Harmonic Imaging
Ophthalmic										
Fetal		P	P	P		P	P	P	P	
Abdominal		P	P	P		P	P	P	P	P
Intraoperative (Specify)										
Intraoperative Neurological										
Pediatric		p	p	p		p	p	p	p	
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Superficial										
Musculo-skeletal Conventional										
Other (specify)										

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; B-TDI; M-TDI

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Jessup

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010631

Prescription Use (Per 21 CFR 801.109)

EXISTING TRANSDUCER TABLE

Transducer Model Number: PLM-1202S
510(k) Control Number: k991710

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal										
Abdominal										
Intraoperative		E	E	E		E	E	E	E	
Intraoperative Neurological										
Pediatric										
Small Organ (Specify)		E	E	E		E	E	E	E	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		E	E	E		E	E	E	E	
Laparoscopic										
Musculo-skeletal Superficial		E	E	E		E	E	E	E	
Musculo-skeletal Conventional		E	E	E		E	E	E	E	
Other (specify)										

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/EWD; BDF/EWD; BDF/MDF; B-TDI; M-TDI

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seyer

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010631

Prescription Use (per 21 CFR 801.109)

EXISTING TRANSDUCER TABLE

Transducer Model Number: PVM-740RT

510(k) Control Number: LTF

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify) –	Harmonic Imaging
Ophthalmic										
Fetal										
Abdominal										
Intraoperative										
Intraoperative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		P	P	P		P	P	P	P	
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Superficial										
Musculo-skeletal Conventional										
Other (specify)										

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/EWD; BDF/EWD; BDF/MDF; B-TDI; M-TDI

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seyer

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K010631

Prescription Use (per 21 CFR 801.109)

EXISTING TRANSDUCER TABLE

Transducer Model Number: PEF-704LA

510(k) Control Number: LTF

Clinical Application		Mode of Operation								
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify) –	Harmonic Imaging
Ophthalmic										
Fetal										
Abdominal										
Intraoperative										
Intraoperative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic		P	P	P		P	P	P	P	
Musculo-skeletal Superficial										
Musculo-skeletal Conventional										
Other (specify)										

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/EWD; BDF/EWD; BDF/MDF; B-TDI; M-TDI

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Seyam

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K010631

Prescription Use (per 21 CFR 801.109)